



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
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<http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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February 10, 2011

Re: Approval Renewal Assurance #A3054-01
Acknowledgement of 2010 Annual Report to OLAW

Horst Simon, Ph.D.
Deputy Laboratory Director
Ernest Orlando Lawrence Berkeley National Laboratory
1 Cyclotron Road, MS 977R250
Berkeley, CA 94720

Dear Dr. Simon,

I am pleased to inform you that the Office of Laboratory Animal Welfare (OLAW) has reviewed and approved the renewal of your Animal Welfare Assurance (Assurance) which was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) revised August 2002. **Your Renewal Assurance bearing the identification number A3054-01 became effective on February 10, 2011 and will expire on December 31, 2014.** This Assurance supersedes all previously approved Assurances.

This letter also acknowledges the receipt and review of your Annual Report to OLAW for calendar year 2010 that was submitted in accordance with Part IV.F. of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals as revised in August 2002.

The Assurance is a key document in defining the relationship of your Institution to the PHS since it sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements which are essential for continued compliance with the PHS Policy. Please note that an Annual Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due January 31st. **Your Annual Report for 2011 will be due to OLAW by January 31, 2012.**

A copy of the approved Assurance signature page is enclosed. Please be sure to reference your Assurance number in all correspondence to this Office. If I may be of further assistance, please feel free to contact me by phone, 301-402-4325, eFax 301-915-9467, or email kt60a@nih.gov.

Sincerely,

Kim Taylor, D.V.M., DACLAM
Senior Assurance Officer
Division of Assurances, OLAW

Encl

cc:

John C. Bartley, D.V.M., Ph.D., IACUC Chair
Dianna Bolt, Ph.D., CPIA, Compliance Specialist

EARNEST ORLANDO LAWRENCE BERKELEY NATIONAL
LABORATORY
A3054-01

ANIMAL WELFARE ASSURANCE
In accordance with the PHS Policy for
Human care and Use of Laboratory Animals

I, Horst Simon, PhD, as the named Institutional Official for animal care and use at Ernest Orlando Lawrence Berkeley National Laboratory, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE.

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the sub-granting or subcontracting of a PHS-conducted or supported activity by this institution.

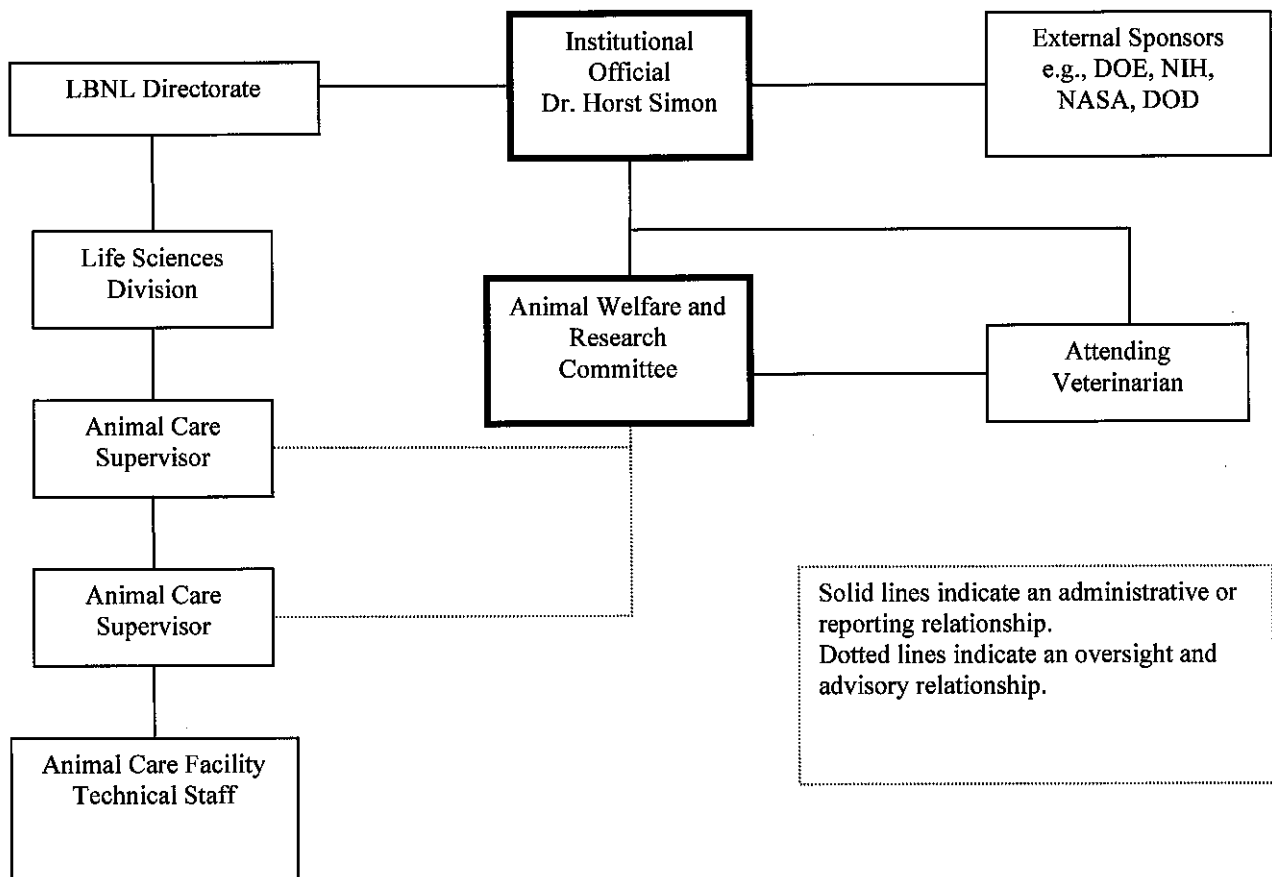
This Assurance covers the entire Institution; there are no branches or subcomponents.

II. INSTITUTIONAL COMMITMENT

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

- A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are:

Name: Nina Hahn

Qualifications:

- Degrees: DVM, MPVM, PhD, Dipl. ACLAM
- Training and/or experience in laboratory animal medicine: LBNL's newly appointed consulting veterinarian, Nina Hahn, DVM, PhD, is trained specifically in Laboratory Animal Medicine. She has more than 20 years experience in the field and currently serves as the Associate Directory of the University of California, Berkeley Office of Laboratory Animal Care. She is a member in good standing of the American Association of Laboratory Animal Science and of the Northern California Branch of this association and has published many papers in the field of laboratory animal medicine.

Authority: The attending veterinarian has program authority and responsibility for the activities involving animals at LBNL, delegated from the institutional official. She has authority to temporarily interrupt and suspend any procedure or animal care practice deemed in violation of Berkeley Lab Guidelines, the Animal Welfare Act, or PHS Policy, section IV.c.1. a-g. to allow time for a full investigation and development of corrective action plan approved by the AWRC. A report detailing the investigation and corrective action plan will be developed as provided under section III.D.4 ND III.D.10. of this Assurance.

The consulting veterinarian reports to the Institutional Official and functions on behalf of the Institution to ensure and help implement a program for animal research that meets ethical and compliance standards.

Time Contributed to Program: Dr. Hahn will be a 20% time consulting veterinarian at LBNL and plans to visit the animal facilities weekly. She will perform routine inspections, assist in and provide training for animal care, and hold additional consults with animal care personnel and investigators as needed. She is participating in designing a newly planned satellite animal facility and, in this regard, is amending, developing, and implementing Standard Operating Procedures to ensure ethical and efficient care and research use of animals. Dr. Hahn will be on emergency call on a 24 hour/day basis. One LBNL Staff Scientist and member of the Animal Welfare and Research Committee, Dr. Katie Brennan, is a veterinarian licensed by the state of California and is available as needed. Dr. Brennan, as acting consulting veterinarian, has delegated authority similar to that of Dr. Hahn, to temporarily interrupt and suspend any procedure or animal care practice deemed in violation of Berkeley Lab Guidelines, the Animal Welfare Act, or PHS Policy, section IV.c.1. a-g. to allow time for a full investigation and development of corrective action plan approved by the AWRC. Additional veterinary care support is supplied by a senior Animal Technician or Animal Health Tech.

C. The Institutional Animal Care and Use Committee (IACUC), (hereinafter called the Animal Welfare and Research Committee or AWRC), at this Institution is properly appointed in accordance with PHS Policy at IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC(AWRC) consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the names, degrees, position titles, specialties and institutional affiliations of the AWRC chairperson and members (Attachment 1). Administrative support for the AWRC is provided by the Human and Animal Regulatory Committees Office (HARC).

D. The IACUC(AWRC) will

1. Review (by a quorum of the AWRC at a convened meeting) at least once every six months the Institutional Program for Humane Care and Use of Animals (the Program), using the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare Act) as a basis for evaluation. The procedures and criteria for conducting the Program review are based on the sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) AWRC Membership and Functions; b) AWRC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); Occupational Health and Safety, and all program issues raised during convened meetings of the AWRC during the previous six months. If program deficiencies are noted during the review, they will be categorized as significant or minor and the AWRC will develop a reasonable and specific plan and proposed schedule for correcting each deficiency. The resulting written report will be discussed and voted on at a convened meeting and minority reports solicited from dissenting members. No member will be involuntarily excluded from participation in any portion of the review.
2. Inspect at least once every six months all of the institution's facilities where animals are housed or used. Equipment used for transporting of animals is also inspected. The Guide and other pertinent resources, e.g., the PHS Policy, and the Code of Federal Regulations (Animal Welfare Act) are used as a basis for evaluation. The AWRC or a designated subcommittee of not less than two voting members will visit each area where animals are housed or used and complete the evaluation form. If facility deficiencies are noted during the inspection, they will be categorized as significant or minor and the AWRC will develop a reasonable and specific plan and proposed schedule for correcting each deficiency. The resulting written report will be discussed and voted on at a convened meeting and minority reports solicited from dissenting members. All IACUC members are required to participate in the

Semiannual Facility Inspections. No member will be involuntarily excluded from participation in any portion of the review.

3. Prepare reports of the AWRC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official (IO). The AWRC process for developing reports and submitting them to the Institutional Official is:

A draft report based on the Program Review, facility evaluation findings, and any additional observations submitted by members will be brought to a convened meeting of the AWRC for discussion. The draft reports will be reviewed, revised as appropriate, and approved by the AWRC. Any departure from the PHS Policy and the "Guide" will be noted and treated as a deficiency. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan for correcting each deficiency. Policies of the AWRC, LBNL's IACUC, do not provide for consideration of requests for departures from PHS policy, the Guide, and AWA regulations.

Deficiencies reported from the Program Reviews and Facility Inspections are triaged into three categories based on OLAW guidance: minor significance, major significance, and major significance reportable to OLAW. All findings are tracked on a spreadsheet and the action items and the individuals or parties responsible for correction are assigned. The final version of the findings and the corrections are approved and progress to completion is assessed by the full IACUC. Correction of facility concerns are verified in the field by a subcommittee of the IACUC that usually includes the chair, the facility manager, and the attending veterinarian.

The final report will be signed by a majority of AWRC members and will include any minority opinions. If there were no minority opinions, the report will reflect this. The completed report will be submitted to the Institutional Official within 60 days following the evaluation. The report will be copied to the Animal Facility Committee (AFC) for correction of action items under their purview.

4. Review concerns involving the care and use of animals at the institution. The AWRC procedures for reviewing concerns are:

The AWRC will review and investigate any concerns or complaints that arise involving the care and use of animals at Berkeley Lab. These include suspension of activities imposed by the Attending Veterinarian (see Sec.B) and reports of concerns by any individual to the IO, AWRC Chair, Attending Veterinarian, any member of the AWRC, or the Lab's Ombudsman. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns. The notices will assure that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. Reporters' wishes concerning

anonymity will be respected. Additionally, the Chair of the AWRC or his/her designee meets with the Animal Colony Manager on a regular basis to discuss animal related health issues. In addition, the Chair and/or Vice Chair and the ACM perform periodic unannounced health surveillance and health log review inspections, reporting concerns to the responsible investigator and bringing ongoing or unresolved problems to the AWRC.

All reported concerns will be brought to the attention of the convened AWRC. If necessary, the AWRC Chair will convene a special meeting to discuss, investigate, and address any reported concern. Any corrective action must either be voted on by a convened quorum of AWRC members, or, if made by the Chair or Attending Veterinarian to correct an imminent hazard, be confirmed by a convened quorum of the AWRC as soon as reasonably possible. Noncompliance, evasion or violation of the Berkeley Lab, NIH, or USDA guidelines for animal use uncovered through this process will fall under the provisions of III.D.10, below, including required reporting to the Institutional Official and OLAW.

The AWRC will review any concerns that arise involving the care and use of animals at Berkeley Lab and make recommendations to the Institutional Official when actions are required with respect to any aspect of the institution's animal program, facilities, or personnel training. Concerns raised during the semi-annual reviews will be reviewed and reported as specified in III.D.3. (above). Concerns that are raised in the periods between reviews and meriting immediate action will be reported to the Institutional Official and the Animal Facility Committee as described above for the program review and site visit (III.D.2.-3.).

5. Written recommendations derived from III D 4 above, are put into a letter, which is considered and approved by the AWRC, signed by the chair, and sent to the Institutional Official for action.
6. In accord with the PHS Policy IV.C.1-3, the AWRC shall review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals. The AWRC procedures for protocol review are:

- a. Meetings, Quorum, and Voting.

AWRC meetings and actions will be in accordance with the general provisions of PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, with the following specific conditions being observed:

- 1) Meetings are held monthly. If an emergency meeting is necessary to insure that the AWRC's actions conform to PHS policy, such a meeting will be called.

- 2) A quorum of the AWRC is defined as a majority of the total current membership. In order for official AWRC business to be conducted, a quorum must be present.
- 3) No member may participate in the AWRC review or approval of an application, proposal, or animal use protocol, in which the member has a conflicting interest (e.g. is personally involved in the project), except to provide information requested by the AWRC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
- 4) The AWRC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the AWRC unless they are also members of the AWRC.

b. Review of all applications and proposals involving use of animals.

The AWRC shall conduct a review of those sections of applications and proposals related to the care and use of animals and determine that the proposed activities are in accordance with the PHS Policy. The investigator must submit an "Animal Use Protocol" to the AWRC for each proposed experiment involving the use of animals. Each protocol must be reviewed by the convened AWRC.

- 1) In determining that the proposed activities are in accord with the PHS policy, the AWRC shall confirm that the activity will be conducted in accord with the Animal Welfare Act insofar as it applies to the activity and that the activity is consistent with the Guide unless acceptable justification for a departure is presented. Further, the AWRC shall determine that the activity conforms with the institution's assurance and meets the following requirements:
 - a) Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.
 - b) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator. This justification must include a description of the sources used to determine that no alternative to this procedure exists.
 - c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

- d) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.
 - e) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 - f) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g) Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
- 2) Prior to the review, each AWRC member shall be provided with a list of applications and proposals to be reviewed.
- a) Approval of Animal Use Protocols or protocol renewals may be granted only after review at a convened meeting of a quorum of the AWRC and with the approval of a majority of the quorum present (see section III.D.6.a.(2)). The committee may then approve, require modification to secure approval or withhold approval of animal use protocols. If the committee requires further modifications and conditions to secure full approval, the committee will assign the process for determining that those conditions have been met. Thus, if required modifications are minor, once they have been made they may be approved by designated member review; however, if substantial modifications are required, then the full protocol with those modifications must be reviewed by the full committee before full approval can be granted. This process applies to the consideration of new protocols, renewal of protocols, or amendment of ongoing protocols. The LBNL Animal Welfare and Research Committee only uses designated member review for the consideration of minor changes made to a protocol that has already been reviewed by the full committee and is in a state of approved pending clarification.

- b) Collaborations with other institutions and organizations are submitted to the AWRC for review and approval as described in section III.D.6.a. These collaborative protocols include the conduct of joint research with a colleague at a different institution where all activities with live animals are conducted at the other institution and contracting with another institution or facility to perform specific animal research. The review ensures that the outside institution will properly house and maintain the animals, holds an approved Assurance of PHS compliance (or, for foreign institutions, equivalent protections), and that the animals were or will be manipulated under an IACUC approved protocol.
 - c) Facility Use Protocols (use of Berkeley Lab radiation or other special facilities for animal experimentation by a non-Berkeley Lab investigator) or requests for Exempt from Review status (use of animal tissues obtained from public sources such as an abattoir) may be reviewed by the Chair, his/her designee, or the Compliance Specialist. Exempt protocols do not permit the use of live animals, and Facility Use protocols permit the use of live animals only when that use has been previously reviewed and approved by the Institutional Animal Care and Use Committee with an approved Assurance of PHS Policy compliance at the visiting investigator's home institution. The reviewer may approve the request or require it to be placed on the agenda for the next convened meeting. At the time of the meeting, any committee member may ask that any Facility Use or Exempt protocols be reviewed and voted on separately as in III.D.6.a. In the absence of a request for full review, all Facility Use or Exempt protocols appearing on the agenda are considered to be approved.
- c. Additional approvals:
- Applications and proposals that have been approved by the AWRC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the AWRC.
7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The AWRC procedures for reviewing proposed significant changes in ongoing research projects are:

The investigator will advise the AWRC of any proposed change or modification in an approved protocol. Such proposals will be reviewed by the AWRC at its next convened meeting. When there are significant changes, review and approval of such changes are handled in the same manner as new protocols. See Paragraph iii.D.6., above.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure AWRC approval as set forth in the PHS Policy at IV.C.4. The AWRC procedures to notify investigators and the institution of its decisions regarding protocol review are:

The AWRC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure AWRC approval. If the AWRC decides to withhold approval of an application or proposal, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Copies of the written notifications shall be maintained in the institutional files in the Human and Animal Regulatory Committee's office.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the AWRC, including a complete review in accordance with the PHS Policy at IV.C. 1-4. at least once every three years. The AWRC procedures for conducting continuing review are as follows:

The AWRC shall conduct annual reviews of each continuing protocol. Annual protocol reviews are recorded in the AWRC meeting minutes, which are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months and expire no later than the three-year anniversary of the initial AWRC approval. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved as described in III.D.6 above.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The AWRC procedures for suspending an ongoing activity are as follows:

The AWRC may suspend an activity only after review of the matter at a convened meeting of a quorum of the AWRC and with the suspension vote of a majority of the quorum present. The report to the Institutional Official provides the results of the investigation and the recommended corrective actions as approved by AWRC.

If the AWRC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Assurance, the Institutional Official in consultation with the AWRC shall review the reasons for suspension, take appropriate corrective action and report that action with a full explanation to OLAW.

- E. The LBNL Medical Director is involved in planning and monitoring the occupational health aspects of the occupational health and safety program for personnel working in laboratory animal facilities or having frequent contact with animals. The LBNL occupational health and safety program is accredited by the Accreditation Association for Ambulatory Health Care, Inc. The program for those personnel working laboratory animal facilities or having frequent contact with animals is based on Risk Assessment and Hazard Identification as described in the *Guide for the Care and Use of Laboratory Animals*. It is in conformance to the institutional Job Hazard Analysis program and adheres to sections of Biosafety for Medical and Biological Laboratories (BMBL) for Animal Biosafety Level 2 when applicable. Institutional policies for personal hygiene, handling hazardous agents, and personnel protection are applicable to all aspects of animal care and handling.

The program is as follows:

1. Animal care personnel are required to have physical examinations every two years. Research staff handling animals have periodic physical examinations whose frequency is determined by their other duties. These examinations include a review of medical history, tuberculosis testing, and the need for individual preventive medical measures such as vaccinations, allergen exposure prevention, and/or special precautions related to preexisting conditions.
2. Staff members entering facilities within the animal colony are required to use personnel protection equipment (PPE --lab coats, scrub suits, gowns, masks, shoe covers and head gear) for their own health protection as well as that of the animals. The PPE requirements are specific to each facility: currently holding areas for a mouse breeding and maintenance facility, and cage washing and sterilizer room and experimental areas for mice, rats, zebrafish, and larger animal imaging.

3. Other health and safety issues such as safety training and awareness, personal hygiene, risk identification and alleviation, and injury/illness reporting requirements are covered by LBNL's Health and Safety Manual that applies to all staff on-site. Our new attending veterinarian will be providing training to LBNL staff on potential zoonotic diseases, development of allergies to laboratory animals, and the hazards associated with handling laboratory animals as well as working in an animal facility. Dr. Hahn will train personnel on precautions to be taken during pregnancy, illness, or decreased immunocompetence. The LBNL Medical Director routinely screens for all positions at LBNL where immunosuppression could constitute a personal health risk.
4. Vaccination for tetanus is required for all Berkeley Lab animal care personnel at hiring and at 10-year intervals thereafter. Vaccination for tetanus is also available to all research personnel handling animals, and investigators are encouraged to institute a tetanus program for their staff members likely to handle animals.
5. Instructions for immediate treatment for bites and scratches is provided in the Animal Care Facility Animal Biosafety Manual, the Medical Imaging Biosafety Manual, and in Standard Operating Procedures specific to the appropriate facility(ies). Follow-up first aid for minor injuries is provided in the LBNL Medical Clinic. Serious or life-threatening injuries would be referred immediately to the local trauma center at Alta Bates Hospital in Berkeley.
6. Staff members coming into contact with primates are required to have a skin test for tuberculosis annually. (Although no primates are housed on site, primates are brought to Berkeley Lab for imaging studies. See item 7 below and the Facilities and Species Inventory for more information.)
7. Screening tests for intestinal parasites and bacterial infections are conducted on staff handling primates when deemed necessary or on request.
8. The facility at LBNL which handles primates, the Animal Imaging Facility (AIF), is covered by a Manual based on the BMBL. This Manual contains the Standard Operating Procedures of the University of California at San Francisco (UCSF) Primate Facility. These SOPs include medical surveillance and screening policies and procedures as well as on-site bite and scratch treatment. A treatment protocol for primate bites has been established and is posted in any Lab facility where contact with primates may occur. There are bite kits and first aid kits at hand in the AIF. The AIF operates under a Biosafety Use Authorized (BUA) from the LBNL Institutional Biosafety Committee (IBC). The primate handlers are exclusively UCSF Primate Colony Staff. Their training is verified as part of the approval process for LBNL Animal Use Protocol. The UCSF Animal Colony is AAALAC accredited and the last site included the AIF at LBNL. Of course, the AIF is inspected as part of the Semiannual Facility inspections by the AWRC.

9. The program for reporting injuries or disease possibly arising from animal care and handling or as a result of work activities in animal facilities is to report them immediately to Medical in compliance with LBNL institutional policies and procedures for such reporting. Additionally, any primate-related injury must be reported to UCSF at the number provided in the Manual and posted in the facility.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory, by species, of animals in each facility is summarized in Attachment 2.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:

A training program has been designed to present material specifically tailored to the four groups of animal users involved: (1) principal investigators and staff scientists; (2) research associates, technicians, post-doctoral scientists; and (3) animal colony staff, and members of the AWRC (LBNL's IACUC) and the Institutional.

New staff members who will be handling animals continue to receive an orientation on the Berkeley Lab animal colony and the *AWRC Guidelines for Users of the LBNL Animal Colony* from the Animal Colony Manager. Staff members have electronic access to guidelines and policies; printed copies are available on request as well as being routinely distributed by the AWRC. All staff must certify that they have read the applicable protocol and the *Guidelines* before beginning research involving animals. Principal investigators certify as part of the protocol approval process that each staff member is adequately trained to perform the research responsibilities allotted to them, and AWRC veterinary members observe staff performing new and/or potentially stressful procedures on an as-needed basis.

The AWRC has established an agreement with the Collaborative Institutional Training Initiative (CITI) to use their on-line training modules for the use of investigators, post-doctoral and staff scientists, and research and animal colony staff, as well as new AWRC members and the Institutional Official. Completion of core units are required of all individuals involved in any aspect of animal research or protocol preparation or review, as identified by the annual LBNL Job Hazards Questionnaire. These core units include training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other additional training requirements of 9 CFR Part 2, Subpart C. Section 2.32(c). Completion of additional on-line units in specialty areas (i.e., research involving mice or rats or primates) is required by the AWRC as a condition of protocol approval on an as-needed basis. The on-line training site maintains a master record of the units and tests completed; these are used by HARC Office staff to prepare training certifications. The first tutorial system, using the Veteran's Administration site,

was implemented in July, 2002. The LBNL training modules were migrated over to CITI in July of 2007.

In addition to the CITI training, AWRC members are informed of new concerns and advances in the field of the ethical treatment of research animals by 1) HARC compliance staff, who attend the annual Public Responsibility in Medicine and Research (PRIM&R) IACUC conference as well as 2) by the Animal Colony Manager who attends the American Association for Laboratory Animal Science in the fall; both report back to the committee at the next regularly scheduled meeting. The consulting veterinarian is invited at every meeting to share recent advances and concerns. The AWRC chair monitors the training offered by the California Biomedical Research Association (CBRA) and the Massachusetts Society for Medical Research and, at least, once a year attends a training covering current concerns for animal welfare and security.

All protocol personnel training is documented annually through the Protocol Personnel Form, a required attachment to both protocol and annual renewal forms.

IV. INSTITUTIONAL STATUS

All of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the AWRC within the past six months and will be reevaluated by the AWRC at least once every six months thereafter, in accord with the PHS Policy IV.B.1. and 2. Reports have been and will continue to be prepared in accord with PHS Policy IV.B.3. All AWRC semiannual reports will include a description of the nature and extent of this institution's adherence to the "Guide". Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the AWRC evaluations will be submitted to the Institutional Official. Semiannual reports of AWRC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

This Institution is category One (1)-- accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). As noted above, reports of the AWRC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:

1. A copy of this Assurance and any modifications thereto, as approved by PHS.

2. Minutes of AWRC meetings, including records of attendance, activities of the committee, and committee deliberations.
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether AWRC approval was given or withheld.
 4. Records of semiannual AWRC reports and recommendations (including minority views) as forwarded to the Institutional Official, Horst Simon, PhD, Deputy Laboratory Director.
 5. Records of accrediting body determinations.
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the AWRC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

- A. This Institution's reporting period is January 1 –December 31. The AWRC, through the Institutional Official, will submit an annual report to OLAW on January 31 each year. The report will include:
1. Any change in the accreditation status of the institution (e.g., if LBNL obtains accreditation by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in AWRC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
 2. Notification of the dates that the AWRC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Horst Simon, PhD, Deputy Laboratory Director.
- B. The AWRC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy.
 2. Any serious deviations from the provisions of the "Guide."

3. Any suspension of an activity by the AWRC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the AWRC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Horst Simon, PhD

Title: Deputy Laboratory Director, Ernest Orlando Lawrence Berkeley National Laboratory

Address: 1 Cyclotron Road, MS 977R250, Berkeley, CA 94720

Phone: 510-495-2438

Fax: 510-495-2535

Email: Horst.Simon@lbl.gov

Signature: 

Date: 2/9/2011

B. PHS Approving Official

Name: Dr. Kim Taylor, DVM, DACLAM
Senior Assurance Officer
Office of Laboratory Animal Welfare
Title: NIH/OD/OER
6705 Rockledge Drive
Address: RKL 1, Suite 360, Room 3609-MSC 7982
Bethesda, Maryland 20892-7982
Phone: 301-402-4325 kt60a@nih.gov

Fax:

Signature: 

Date: 2/10/11

C. Effective Date of Assurance: 2/10/11

D. Expiration Date of Assurance: 12/31/14

Attachment 1: MEMBERSHIP, INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

NAME OF INSTITUTION: Ernest Orlando Lawrence Berkeley National Laboratory
 ASSURANCE NUMBER: A 3054-01

Chairperson Name, Title and Degree/Credentials	Business Address, Phone Fax and Email of Chairperson
John C. Bartley, Chair Title: Environment, Health and Safety Specialist	Address: Animal Welfare and Research Committee MS 26R0143 1 Cyclotron Road Berkeley, CA 94720
Degree/credentials: DVM, PhD	Phone: 510-486-4191 Fax: 510-486-6949 Email: jcbartley@lbl.gov

Name of Member*	Degree/credentials	Position Title	PHS Policy Membership Requirements
1. John C. Bartley, Chair	DVM, PhD	Retired/rehired EH&S Specialist	Chairperson
2. 2	PhD	Senior Staff Scientist	Vice Chair, Researcher
3. Nina Hahn	DVM, PhD	Attending Veterinarian	Veterinarian
4. 4	DVM	Staff Scientist	Researcher
5. 5	PhD	Staff Scientist	Researcher
6. 6	PhD	Staff Scientist	Researcher
7. 7	BS	Public Member, lay religious leader	Public (Unaffiliated) Member
8. 8	DD	Public Member, alternate, ethicist,	Public Member Alternate
9. 9	PhD	Staff Scientist	Researcher Alternate
10. 10	MA	Lead Compliance Specialist	Non-Scientist
11. 11 (Ex officio)	BS	Animal Colony Manager	Non-Voting
12. 12	PhD, CPIA	Compliance Specialist	Non-Voting

Attachment 2: FACILITY AND SPECIES INVENTORY

Date: 08/31/2010

NAME OF INSTITUTION: Ernest Orlando Lawrence Berkeley National Laboratory

ASSURANCE NUMBER: A 3054-01

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use complete common names)	Approx. Average Daily Inventory
Building 86	5000	Mice	3000
		Rats	52
		Rabbits	0
		Dogs	0
Building 55	1000	Imaging facility and prep areas	Approx. 1-2 primates/month*
Building 70A	400	Temporary housing facility for mice	Groups of 100 for a 2 week period; not continuous
Building 80	400	Zebrafish	30

* Primates are brought to Berkeley Lab for imaging studies. No primates remain on site longer than six hours, and all imaging studies must be covered by approved protocols and/or collaborative agreements.